UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In re LANTUS DIRECT PURCHASER ANTITRUST LITIGATION

CIVIL ACTION NO. 16-12652-JGD

MEMORANDUM OF DECISION AND ORDER ON DEFENDANT'S MOTION TO DISMISS CERTAIN CLAIMS FOR LACK OF ARTICLE III STANDING

December 22, 2020

DEIN, U.S.M.J.

I. <u>INTRODUCTION</u>

Plaintiff FWK Holdings, LLC ("FWK") is a direct purchaser of the insulin glargine products

Lantus and Lantus SoloSTAR, which are used to treat Type I and Type II diabetes. It has brought
this putative class action against Sanofi-Aventis U.S. LLC ("Sanofi"), the manufacturer of both
products, alleging that Sanofi engaged in anticompetitive conduct as part of an overall scheme
to prevent or delay competitors from entering the market for insulin glargine and charge
supracompetitive prices for its Lantus products. FWK alleges that Sanofi carried out this
scheme by improperly listing patents in the U.S. Food and Drug Administration's book of

Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") and
then taking advantage of its consequent right to file patent infringement actions against
aspiring competitors in an effort to block competition before any competing product reached
the market. By its Second Amended Class Action Complaint ("SAC"), FWK is seeking to hold
Sanofi liable for monopolization and attempted monopolization under Section 2 of the Sherman
Act, 15 U.S.C. § 2. It is undisputed that the plaintiff made no purchases of Lantus or Lantus

SoloSTAR after May 2016. However, FWK aims to pursue its claims on behalf of itself and a class consisting of "[a]II persons or entities in the United States and its territories, or subsets thereof, that purchased Lantus (in cartridges or SoloSTAR) directly from Sanofi at any time between February 13, 2015 and December 31, 2016 or until the anticompetitive effects of Sanofi's conduct cease (the 'class')."

The matter is presently before the court on "Defendant Sanofi-Aventis U.S. LLC's Motion to Dismiss Certain Claims for Lack of Article III Standing" (Docket No. 152), by which Sanofi is seeking dismissal of FWK's claims, pursuant to Fed. R. Civ. P. 12(b)(1), to the extent they are based on conduct that occurred after June 2016. The conduct at issue includes Sanofi's submission of patent information to the Food and Drug Administration ("FDA") for inclusion in the Orange Book after June 2016 and the defendant's filing of patent infringement actions against Merck Sharp & Dohme Corp. ("Merck") and Mylan N.V. and its affiliates (collectively, "Mylan"). Sanofi contends that because FWK had ceased all purchases of Lantus products by the time these events took place, it could not have sustained any resulting injury. Therefore, Sanofi argues that FWK cannot establish standing to pursue these claims under Article III of the Constitution.

Sanofi's motion is premised on the contention that the post-June 2016 Orange Book listings and the Merck and Mylan litigations are distinct events, and that the named plaintiff must have suffered injury as a result of each event in order to have standing to pursue it as part of its claims. However, this contention is not supported by a fair reading of the SAC. As an initial matter, some of the patents at issue in the Merck and Mylan lawsuits were listed in the Orange Book prior to June 2016 so that their listing could have caused FWK direct harm by

dissuading putative competitors from seeking to enter the market earlier and/or by giving

Sanofi the means to bring an infringement action against Eli Lilly & Company in 2014.

Moreover, FWK has alleged a continuous scheme on the part of Sanofi to keep competitors out of the marketplace by filing meritless litigation within the exclusive period triggered by the

Orange Book listings. Thus, the Merck and Mylan litigation are further examples of the same scheme that caused the plaintiff and class members harm prior to June 2016, and continued to cause harm to class members after June 2016. They are not separate and distinct claims requiring the named plaintiff to have personally suffered resulting injury.

Admittedly, the question raised by Sanofi in its motion is a close one given the lack of clarity in the law of standing vis-à-vis class action representation. Nevertheless, this court finds that at this stage in the litigation FWK has alleged sufficient facts to establish Article III standing with respect to Sanofi's post-June 2016 conduct. Therefore, and for all the reasons detailed below, the defendant's motion to dismiss is DENIED.

II. STATEMENT OF FACTS

Sanofi has brought its motion to dismiss pursuant to Rule 12(b)(1) of the Federal Rules of Civil Procedure. Rule 12(b)(1) is "[t]he proper vehicle for challenging a court's subject-matter jurisdiction" including a claim, such as the one made by Sanofi, that the plaintiff lacks Article III standing. See Valentin v. Hosp. Bella Vista, 254 F.3d 358, 362 (1st Cir. 2001). In assessing jurisdiction under Rule 12(b)(1), the court "must take the complaint's well-pleaded facts as true and indulge all reasonable inferences in the pleader's favor[.]" Hochendoner v. Genzyme Corp., 823 F.3d 724, 730 (1st Cir. 2016). The court may consider materials outside the complaint to the extent they shed light on the jurisdictional analysis. See Gonzalez v. United States, 284 F.3d

281, 288 (1st Cir. 2002) ("While the court generally may not consider materials outside the pleadings on a Rule 12(b)(6) motion, it may consider such materials on a Rule 12(b)(1) motion"); Valentin, 254 F.3d at 364 ("when a factbound jurisdictional question looms, a court must be allowed considerable leeway in weighing the proof, drawing reasonable inferences, and satisfying itself that subject-matter jurisdiction has attached"). Because this court's analysis requires a comprehensive understanding of the plaintiff's theories, a fairly detailed description of the allegations of the SAC follows.

The Parties

FMK commenced this action in December 2016. (Docket No. 1). Shortly thereafter, Cesar Castillo, Inc. ("Cesar Castillo") filed a related case against Sanofi, and the two actions were consolidated at the request of the parties. (Docket No. 8 at 2; Docket No. 13). On August 31, 2020, Cesar Castillo voluntarily dismissed all its claims against the defendant, leaving FWK as the only named plaintiff in the case. (Docket No. 127). FWK is an Illinois corporation and the assignee of the claims of Frank W. Kerr Co. ("Kerr"). (SAC (Docket No. 51) ¶ 14). It is undisputed that FWK's ability to assert claims against Sanofi, and its status as a direct purchaser of Sanofi's products, rest on Kerr's purchases of Lantus and Lantus SoloSTAR during the proposed class period. (See SAC ¶ 14). Kerr's last purchase occurred in May 2016, at least seven months before the end of the proposed class period and shortly before Kerr began to wind down its operation in June 2016. (Coughlin Decl. ¶ 3;¹ SAC ¶ 486; Debtor's First Day Motion for Order Authorizing Use of Cash Collateral and Granting Adequate Protection on an

¹ The "Coughlin Decl." refers to the Declaration of Theresa M. Coughlin in Support of Defendant Sanofi-Aventis U.S., LLC's Opposition to Plaintiffs' Motion to Compel (Docket No. 130-1).

Interim Basis Pending Final Appeal at 3, In re Frank W. Kerr Company, No. 16-51724-mlo (Bankr. E.D. Mich. Sept. 20, 2016), ECF No. 31). At issue is whether FWK has standing to maintain claims based on alleged anticompetitive conduct that occurred after Kerr's purchases ceased.

The defendant, Sanofi, is a life sciences company that sells medications, including insulin glargine under the trademark "Lantus." (See SAC ¶ 3). Lantus is sold in vial form and in an injector pen known as Lantus SoloSTAR. (Id.). Sanofi first obtained approval from the FDA to sell Lantus in 2000. (Id.). Its original patent for insulin glargine, U.S. Patent No. 5,656,722 (the "722 Patent"), as extended by a period of pediatric exclusivity, expired on February 12, 2015. (Id. ¶¶ 178-81). FWK claims that this "ended Sanofi's lawful exclusivity for insulin glargine" and "follow-on competition from other insulin glargine products should have entered the U.S. market" at that point. (Id. ¶ 3). However, according to the plaintiff, Sanofi took advantage of the statutes and regulations governing patented drug products to unlawfully extend its period of market exclusivity over insulin glargine and charge supracompetitive prices for Lantus and Lantus SoloSTAR after February 2015. (See id. ¶¶ 5, 9-12, 285-88, 385).

Sanofi's Allegedly Unlawful Scheme

As described above, FWK alleges that Sanofi carried out an anticompetitive scheme by improperly listing patents in the FDA's Orange Book and filing meritless patent infringement actions against potential competitors. A detailed description of the statutes and regulations governing the FDA's process for listing patents in the Orange Book is unnecessary for purposes of this decision. What follows is a brief summary of that process, along with an explanation as to how the listings relate to Sanofi's alleged scheme.

The Orange Book Listings

The Orange Book is intended to put drug manufacturers on notice of relevant patents. When a drug manufacturer seeks FDA approval of a new drug by filing a new drug application, or applies for approval of changes to a previously approved drug by filing a supplemental new drug application, it must comply with the requirements of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. ("FDCA"), as amended by what are commonly known as the Hatch-Waxman Amendments.² In re Lantus Direct Purchaser Antitrust Litig., 950 F.3d 1, 3 & n.1 (1st Cir. 2020). Under the statute,

the manufacturer must "file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."

<u>Id.</u> at 3(quoting 21 U.S.C. § 355(b)(1)). "Upon accepting the submission, the FDA then lists the patent in the Orange Book." <u>Id.</u> This establishes a "centralized source from which would-be competitors [can] determine which patents a brand company [believes protect] its drug product, formulation, or method of using the drug product." (SAC ¶ 126).

According to FWK, the FDA must list any patents the drug manufacturer identifies, and the agency conducts no substantive evaluation to determine whether those patents meet the statutory criteria. (Id. ¶ 27). See also In re Lantus, 950 F.3d at 3 (noting that the FDA conducts no review of patent submissions other than checking for completeness and looking to confirm

² The Hatch-Waxman Amendments refer to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, which is codified at 21 U.S.C. § 355 and 35 U.S.C. § 271(e). <u>In re Lantus Direct Purchaser Antitrust Litig.</u>, 950 F.3d 1, 3 n.1 (1st Cir. 2020).

that a patent "is not facially ineligible for listing"). The FDA does require the manufacturer to file a declaration verifying "that the submitted patent claims the 'drug substance,' 'drug product (composition/formulation),' or 'one or more methods of using' the drug for which it is listed." In re Lantus, 950 F.3d at 4 (quoting 21 C.F.R. § 314.53(c)(2)(i)(M)-(O)). However, it relies on the manufacturer's truthfulness about whether the patent claims a drug product or method of using a drug product, and whether an infringement claim could reasonably be asserted against a competitor. (SAC ¶ 34). FWK alleges that Sanofi repeatedly submitted patents for listing in the Orange Book that failed to meet the applicable requirements. (See id. ¶¶ 261-77, 279-83, 389-403). As further described below, that practice allegedly continued well beyond the time when Kerr stopped purchasing Lantus products.

Significance of the Orange Book Listings

"The Orange Book listing comes into play when another manufacturer seeks FDA approval to sell a competing drug based on the safety and efficacy studies for the original, already-approved drug" produced by the brand manufacturer. In re Lantus, 950 F.3d at 4. Although this process makes it easier and quicker for aspiring competitors to obtain FDA approval of follow-on or generic versions of an existing drug, it also requires the applicant to specify how its product relates to the brand manufacturer's patents. (See SAC ¶¶ 71-74). Specifically, for each patent listed in the Orange Book, the aspiring competitor must certify "that (1) the patent has expired, (2) the competing manufacturer will wait for the patent to expire before marketing its competing product, or (3) the listed patent is invalid, unenforceable, or will not be infringed." In re Lantus, 950 F.3d at 4 (citing 21 U.S.C. §

355(b)(2)(A)(i)-(iv)). The last of these certifications, known as a "Paragraph IV certification," is relevant to this case.

"A Paragraph IV certification has two direct effects on the resolution of any patent dispute between the original manufacturer and the putative competitor." Id. First, under the Hatch-Waxman Amendments, the filing of a Paragraph IV certification is treated as an act of technical infringement of the listed patent and provides the brand manufacturer an opportunity to sue prior to FDA approval of the competing product. (See SAC ¶¶ 79, 128). See also 21 U.S.C. § 355(c)(3)(C); 35 U.S.C. § 271(e)(2)(A). Ordinarily, patent holders whose products do not qualify for listing in the Orange Book must wait until an allegedly infringing product reaches the market to sue the alleged infringer. (See SAC ¶ 287). Under the Hatch-Waxman Amendments, drug manufacturers whose products satisfy the listing requirements may file infringement suits before a competitor has a chance to enter the market. (See id. ¶ 128). See also 21 U.S.C. § 355(c)(3)(C). Second, if the brand manufacturer "initiates a patent infringement action against its would-be competitor within forty-five days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval to the [putative competitor's application] until the earlier of (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the [new] product." (SAC ¶ 80). See also 21 U.S.C. § 355(c)(3)(C). FWK contends that this process enables branded drug manufacturers to

game the system by describing patents as containing drug product claims (even if the patents, in fact, do not do so), and then suing a would-be competitor that files a paragraph IV certification, even though that lawsuit lacks all merit (i.e, even if the competitor's product does not actually infringe any properly listed patent).

(SAC ¶ 155). Because the filing of an infringement action automatically prevents the FDA from approving an aspiring competitor's application for up to 30 months, FWK asserts that brand manufacturers are able to delay the introduction of competing products regardless of the appropriateness of their Orange Book listings or validity of the lawsuit. (Id. ¶¶ 155-56). The plaintiff claims that Sanofi improperly exploited this opportunity to block competition and keep prices for its Lantus products high. (See id. ¶¶ 4-9, 11-12).

Sanofi's Allegedly Wrongful Listing of Patents in the Orange Book

As noted above, Sanofi is the holder of the '722 Patent for insulin glargine, which is used in the treatment of diabetes. (Id. ¶¶ 178-80). Sanofi sold insulin glargine for use as an injection under the name Lantus. (Id. ¶ 184). It also listed the '722 Patent in the Orange Book. (Id. ¶ 183). The '722 Patent period, as extended, expired on February 12, 2015. (Id. ¶ 181). FWK "does not challenge Sanofi's rights to charge supra-competitive prices for Lantus products up until February of 2015. But it does challenge Sanofi's unlawful conduct in prolonging its exclusive position beyond February of 2015, i.e., beyond the expiration of the '722 [P]atent." (Id. ¶ 197).

When Lantus was originally approved by the FDA, it had two package forms: vials for use with single-dose syringes, and cartridges for use in an injector pen Sanofi called "OptiPen ™ One." (Id. ¶ 186). In 2006 Sanofi obtained FDA approval of the Lantus SoloSTAR, a new disposable insulin pen device. (Id. ¶¶ 203-04). As described in detail in the Second Amended Complaint, FWK claims that Sanofi subsequently listed at least 20 patents in the Orange Book that did not meet the listing criteria of the Hatch-Waxman Amendments. (See id. ¶¶ 239-43, 266-77, 285-86, 389-403). Sanofi began listing these patents in 2009 and continued through

late November 2017. (See id. ¶¶ 239, 402). The plaintiff alleges that these listings were improper because two of the patents did not accurately reflect the product formulations contained in Sanofi's applications to the FDA, and the remaining patents claimed packaging relating to the Lantus SoloSTAR rather than a drug or method of using such drug. (See id. ¶¶ 240-42, 266-77, 286, 389, 403).³

Sanofi's Alleged Use of the Orange Book Listings to Block Competition from Eli Lilly

As described above, Orange Book listings come into play when a potential competitor seeks to streamline the drug approval process by relying on the original drug manufacturer's safety and efficacy studies. In late 2013, Eli Lilly & Company ("Lilly") sought FDA approval to market an insulin glargine product known as Basaglar. (Id. ¶¶ 301, 305). Basaglar, like the Lantus SoloSTAR, provides insulin glargine in an injector pen. (See id.). Lilly planned on using its own patented pen for the product, the KwikPen, which Lilly had already been using for other products. (Id. ¶¶ 300, 305). In its application, Lilly relied on Sanofi's safety and efficacy studies for Lantus. (Id. ¶ 302).

Because Lilly relied on Sanofi's FDA submissions, it had to file certifications relating to the patents listed by Sanofi in the Orange Book. On December 18, 2013, Lilly filed certifications regarding all the listed patents for Lantus and Lantus SoloSTAR. (Id. ¶ 306). With respect to the original patent for insulin glargine, the '722 Patent, Lilly agreed to wait to market its product until after the patent and the period of pediatric exclusivity expired in February 2015. (Id. ¶¶ 306-07). With respect to the remaining patents, Lilly filed Paragraph IV certifications stating

³ The First Circuit has already ruled that Sanofi improperly listed one of these patents, United States Patent No. 8,556,864, which was issued on October 15, 2013, in the Orange Book. <u>In re Lantus</u>, 950 F.3d at 10.

that they were "invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of [Basaglar]."⁴ (<u>Id.</u> ¶ 306). Sanofi responded by suing Lilly for infringement of four of the patents in January 2014. (<u>Id.</u> ¶ 325). Pursuant to the Hatch-Waxman Amendments, the lawsuit automatically stayed the FDA's ability to approve Basaglar until the earlier of a ruling on the merits of the lawsuit or May 16, 2016. (<u>See id.</u> ¶ 326). <u>See also</u> 21 U.S.C. § 355(c)(3)(C). On September 28, 2015, the morning of trial, Sanofi and Lilly settled the litigation. (SAC ¶ 375). As part of the settlement, Sanofi granted Lilly a royalty-bearing license that allowed Lilly to manufacture and sell Basaglar, and Lilly agreed to delay the launch of its product until December 15, 2016. (<u>Id.</u> ¶ 375-76).

FWK claims that the litigation was improper because it was based on unlawful Orange Book listings and because there was no merit to Sanofi's infringement claims. (See id. ¶¶ 326-28). It further claims that were it not for the defendant's anticompetitive conduct, "the FDA would have granted Lilly final approval for Basaglar as soon as the '722 [P]atent's pediatric exclusivity expired in February 2015" and "Lilly would have launched Basaglar at prices discounted from those of the Lantus products[.]" (Id. ¶ 371; see also id. ¶ 453). Additionally, according to FWK, Kerr would have purchased insulin glargine from Lilly had it been available during the proposed class period. (Id. ¶ 14).

Continuation of Sanofi's Alleged Scheme Following Kerr's Last Purchase of Lantus

Following resolution of the litigation with Lilly, Sanofi allegedly continued to carry out its anticompetitive scheme. As FWK claims in its Second Amended Complaint, "[e]ven after

⁴ On January 23, 2014, Lilly amended its notice of Paragraph IV certifications to add an additional patent to the list of patents Lilly claimed were invalid, unenforceable and/or would not be infringed by Basaglar. (SAC ¶ 311).

Sanofi's litigation with Lilly, [Sanofi] expected other companies would soon seek to create affordable follow-on insulin glargine products. To further frustrate those efforts, Sanofi obtained and then listed in the Orange Book an additional thirteen patents over its SolarSTAR injector pen" (the "new injector pen patents"). (Id. ¶ 389 (emphasis omitted)). The plaintiff alleges that "[n]one of the new patents claim insulin or insulin glargine. Each one claims one or more aspects of the SoloSTAR packaging. All are improperly listed in the Orange Book and serve to frustrate competition." (Id. ¶ 403). In May 2016, after Sanofi had listed three of the new injector pen patents in the Orange Book, Kerr made its last purchase of Lantus products from Sanofi. (Id. ¶¶ 390-92; Coughlin Decl. ¶ 3). The ten remaining new injector pen patents were listed in the Orange Book between September 15, 2016 and November 28, 2017. (Id. ¶¶ 393-402).

Sanofi filed two additional infringement actions against potential competitors, Merck and Mylan, after Kerr's purchases ceased. (See id. ¶¶ 404-11, 430-34). FWK claims that both lawsuits, like the lawsuit against Lilly, were based on Sanofi's improper Orange Book listings, lacked merit and were motivated by Sanofi's desire to block competition in the market for insulin glargine. (See id. ¶¶ 11, 404, 412, 435, 444-45, 450). The first lawsuit, the Merck infringement action, was filed approximately four months after Kerr made its last purchase of Lantus. (See id. 411; Coughlin Decl. ¶ 3). On May 31, 2016, Merck submitted an application with the FDA seeking approval to manufacture, market and sell an insulin glargine product under the name Lusduna. (SAC ¶ 405). On August 4, 2016, Merck submitted a Paragraph IV certification concerning the patents that were listed in the Orange Book as covering Lantus and Lantus SoloSTAR, and Sanofi responded by filing an infringement action against Merck on

September 16, 2016. (Id. ¶¶ 406-07, 411). The lawsuit encompassed some of the same patents that had been at issue in the Lilly litigation.⁵ (See id. ¶¶ 325, 344, 356, 406-07, 411, 418, 421). Moreover, as in the case of the Lilly litigation, Sanofi's filing of an action against Merck triggered the 30-month stay established by the Hatch-Waxman Amendments. (Id. ¶ 423). This meant the FDA could not approve Lusduna until the earlier of March 2019 or a final judgment in Merck's favor on Sanofi's infringement claims. (Id.). The lawsuit eventually settled following a trial on some of the challenged patents. In re Lantus, 950 F.3d at 6.

The dispute with Mylan arose in 2017. In about August or September of that year, Mylan filed an application seeking the FDA's permission to manufacture, market and sell a follow-on version of Lantus SoloSTAR. (SAC ¶ 430). Accompanying the application was a Paragraph IV certification in which Mylan asserted that the patents listed in the Orange Book as covering Lantus were invalid, unenforceable or would not be infringed by Mylan's product. (Id.). On October 24, 2017, Sanofi filed suit against Mylan alleging that Mylan's proposed follow-on product infringed 18 of its patents, including all the patents that had been involved in the infringement action against Lilly. (Id. ¶¶ 325, 344, 356, 425, 434). Because Sanofi filed suit within 45 days of receiving Mylan's Paragraph IV certification, the FDA was automatically prohibited from approving Mylan's follow-on product until the earlier of March 18, 2020 or a final judgment in Mylan's favor on Sanofi's infringement claims. (Id. ¶ 435). See also 21 U.S.C.

⁵ At the time Sanofi commenced its action against Merck, the patents at issue included six of the patents involved in the Lilly litigation. (See SAC ¶¶ 325, 344, 356, 406-07, 411). Sanofi subsequently amended its complaint and dropped claims as to three of those patents. (Id. ¶¶ 418, 421).

§ 355(c)(3)(C). A bench trial was held in December 2019, and the court issued a ruling in Mylan's favor in March 2020. The matter is now on appeal. ⁶

FWK alleges that the defendant's lawsuits "were nothing but tools to delay competition" by enabling Sanofi to take advantage of the statutory stay. (SAC ¶ 450). In particular, FWK claims that the infringement actions against Lilly, Merck, and Mylan "were not motivated by a genuine desire to protect its . . . intellectual property[,]" but instead "were intended to – and did – frustrate competition in the market for Lantus and insulin glargine." (Id. ¶¶ 444-45).

According to the plaintiff, Sanofi's "overarching anticompetitive scheme impaired and delayed the sale of competing insulin glargine products in the United States, and unlawfully enabled Sanofi to sell Lantus and Lantus SoloSTAR products at artificially inflated prices." (Id. ¶ 452).

Moreover, its successful ability to block competition was "hugely lucrative[,]" amounting to "hundreds of millions more in sales than Sanofi could have achieved absent its unlawful scheme[.]" (Id. ¶ 451).

Alleged Harm to Plaintiff and Members of the Putative Class

FWK claims that were it not for Sanofi's anticompetitive conduct, including its improper listing of patents in the Orange Book and filing of lawsuits against would-be competitors, the plaintiff and members of the proposed class "would have purchased lower-priced insulin glargine products for some or all of their insulin glargine product requirements, and/or would have received lower prices on some or all of their remaining Lantus or Lantus SoloSTAR

⁶ A bench trial took place in the Mylan litigation in December 2019, after the SAC in this case was filed. <u>See In re Lantus</u>, 950 F.3d at 6. In an unpublished decision dated March 9, 2020, the court ruled that Sanofi had failed to prove that Mylan's product infringed on one of Sanofi's patents, U.S. Patent No. 9,526,844 (the "'844 Patent"), and that Mylan had proved that the asserted claims of the '844 Patent were invalid. See <u>Sanofi-Aventis U.S. LLC v. Mylan GmbH</u>, No. 17-9105(SRC), 2020 WL 1151191, at *1 (D.N.J. Mar. 9, 2020). The matter is now pending on appeal at the U.S. Court of Appeals for the Federal Circuit. No. 21-1262.

purchases, at earlier periods of time and in far greater quantities." (Id. ¶ 503). Accordingly, FWK and the proposed class allegedly sustained injuries consisting of "(a) being denied the opportunity to purchase lower-priced insulin glargine products; and (b) paying higher, supracompetitive prices for Lantus and Lantus SoloSTAR than they would have paid in the absence of Sanofi's conduct." (Id. ¶ 514). By its Second Amended Complaint, FWK is seeking to hold Sanofi liable for monopolization and attempted monopolization under section 2 of the Sherman Act, 15 U.S.C. § 2. Additionally, it is seeking to pursue its claims on behalf of itself and a class consisting of "[a]II persons or entities in the United States" who "purchased Lantus (in cartridges or SoloSTAR) directly from Sanofi at any time between February 13, 2015 and December 31, 2016 or until the anticompetitive effects of Sanofi's conduct cease[.]" (Id. ¶ 486).

Additional factual details relevant to this court's analysis are described below where appropriate.

III. <u>ANALYSIS</u>

A. Standard of Review of Article III Standing

"Article III standing is an 'indispensable part' of any case that must be present at every stage of the case." In re Nexium Antitrust Litig. ("Nexium II"), 777 F.3d 9, 31 (1st Cir. 2015) (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 561, 112 S. Ct. 2130, 2136, 119 L. Ed. 2d 351 (1992)). It assures respect for the constitutional requirement that federal court jurisdiction be limited to actual "'Cases' and 'Controversies.'" Hochendoner, 823 F.3d at 731 (quoting U.S. Const. art. III, § 2, cl. 1). Supreme Court precedent has "established that the 'irreducible constitutional minimum' of standing consists of three elements." Spokeo, Inc. v. Robins, --- U.S. ----, 136 S. Ct. 1540, 1547, 194 L. Ed. 2d 635 (2016) (quoting Lujan, 504 U.S. at 560, 112 S. Ct. at

2136). "The plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." Id. As the party invoking a federal court's jurisdiction, the plaintiff "bears the burden of establishing these elements." Id. Where, as here, the question of standing is based on the pleadings, "the plaintiff bears the burden of establishing sufficient factual matter to plausibly demonstrate his standing to bring the action." Hochendoner, 823 F.3d at 731.

Sanofi seeks to dismiss FWK's claims to the extent they are based on conduct that occurred after June 2016, including patent information that the defendant subsequently submitted to the FDA for inclusion in the Orange Book and the two infringement actions that Sanofi filed against Merck and Mylan (the "Conduct"). (Def. Mem. at 1).⁷ "To establish injury in fact, a plaintiff must show that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" Spokeo, 136 S. Ct. at 1548 (quoting Lujan, 504 U.S. at 560, 112 S. Ct. at 2136). Sanofi argues that because it is undisputed that Kerr was winding down its operations and had ceased all purchases of Lantus and Lantus SoloSTAR by June 2016, FWK cannot plausibly allege or prove that it suffered an injury in fact that is traceable to the Conduct. (Def. Mem. at 1-2; Def. Reply Mem. at 1-2).⁸ As detailed more fully below, FWK has alleged that it was harmed by Sanofi's alleged scheme of improperly listing patents in the Orange Book and thereby having a head start in filing infringement actions against would-be competitors. The fact that the scheme

⁷ "Def. Mem." refers to the Memorandum of Law in Support of Defendant Sanofi-Aventis U.S. LLC's Motion to Dismiss Certain Claims for Lack of Article III Standing (Docket No. 153).

⁸ "Def. Reply Mem." refers to the Reply Memorandum of Law in Support of Defendant's Motion to Dismiss Certain Claims for Lack of Article III Standing (Docket No. 164).

continued after Kerr ceased its business so that other class members suffered direct injury thereafter does not preclude FWK from pursuing this claim.

The fact that FWK is seeking to litigate this case as a class action does not alter its obligation to establish Article III standing. See Spokeo, 136 S. Ct. at 1547 n.6 ("That a suit may be a class action . . . adds nothing to the question of standing, for even named plaintiffs who represent a class must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong." (quotations and citations omitted)). However, the question whether allegations of personal injury are sufficient to satisfy the constitutional requirements "is not so clear cut with respect to putative class representatives in class action disputes." In re Nexium (Esomeprazole) Antitrust Litig. ("Nexium I"), 968 F. Supp. 2d 367, 403-04 (D. Mass. 2013). See also Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp., 632 F.3d 762, 768 (1st Cir. 2011) (acknowledging that it was "not so simple" to determine if named plaintiffs in class action could bring suit based on securities offerings in which they did not participate and against trusts whose certificates they did not purchase). The First Circuit has "trained [the] Article III focus in class actions on 'the incentives of the named plaintiffs to adequately litigate issues of importance to them." In re Asacol Antitrust Litig., 907 F.3d 42, 48-49 (1st Cir. 2018) (quoting Plumbers' Union, 632 F.3d at 770). Thus, the plaintiff must possess "such a personal stake in the outcome of the controversy as to assure . . . concrete adverseness." Id. at 49 (quoting Baker v. Carr, 369 U.S. 186, 204, 82 S. Ct. 691, 703, 7 L. Ed. 2d 663 (1962)). Such incentives will be present where "the claims of the named plaintiffs parallel those of the putative class members in the sense that, assuming a proper class is certified, success on the [named

plaintiffs' claims] will more or less dictate success [on the putative class members' claims]." See id.; Nexium I, 968 F. Supp. 2d at 407 (finding that named plaintiffs established standing to maintain class claims against drug manufacturer for anticompetitive conduct where "identity of issues" and "alignment of incentives" were present among members of the putative class).

In order to establish standing in this context, named plaintiffs are not required to show that their claims are identical to the claims of the putative class members. In re Asacol, 907 F.3d at 49. See also Gratz v. Bollinger, 539 U.S. 244, 262-65, 123 S. Ct. 2411, 2423-25, 156 L. Ed. 2d 257 (2003) (allowing named plaintiff in a class action to challenge university admissions practices applicable to incoming freshmen even though he would have applied as a transfer student subject to different rules). Demanding such a showing "would 'confuse[] the requirements of Article III and Rule 23" of the Federal Rules of Civil Procedure by rendering superfluous the commonality and predominance requirements necessary to certify a class under Rule 23. In re Asacol, 907 F.3d at 49 (quoting Fallick v. Nationwide Mut. Ins. Co., 162 F.3d 410, 421 (6th Cir. 1998))(alteration in original). This is because "any case that survived such a strict Article III analysis would by definition present only common issues" in the class certification context. Id. Therefore, the question for standing purposes is not whether there are "differences between the claims of the class members and those of the class representative" but rather whether "the differences that do exist [are] the type that leave the class representative with an insufficient personal stake in the adjudication of the class members' claims." Id. As detailed herein, in light of the plaintiff's allegation of a common, continuing scheme, the fact that some of the conduct continued after Kerr ceased business does not defeat the plaintiff's standing to assert these claims.

B. FWK's Standing in This Case

The issue raised by Sanofi's motion is not whether the plaintiff has standing to pursue its own claims in this case, but whether it has standing to maintain claims on behalf of the proposed class. There is no dispute that FWK has standing to litigate its own antitrust claims based on Sanofi's actions prior to June 2016. As detailed above, FWK has alleged that it was harmed because prior to winding down its business operations in 2016, Kerr had to pay far higher prices for Lantus and Lantus SoloSTAR than it would have paid in the absence of Sanofi's anticompetitive conduct. (See SAC ¶ 505). Thus, it has plausibly alleged a concrete injury that is fairly traceable to the defendant's pre-June 2016 conduct. See In re Asacol, 907 F.3d at 47 (noting that named plaintiffs had standing to maintain their own claims against the defendant where they "plausibly allege[d] an injury in the form of lost money fairly traceable to an allegedly unlawful supra-competitive price, and [sought] classic redress in the form of a damage award"). This distinguishes the present case from situations in which named plaintiffs lack standing to sue on behalf of a class because they cannot link their own harm to a defendant's alleged wrongdoing. See, e.g., Barry v. St. Paul Fire & Marine Ins. Co., 555 F.2d 3, 13 (1st Cir. 1977) (named plaintiffs seeking to represent classes of doctors and patients in antitrust case against four insurance companies could not maintain claims against two of the defendants where there was no evidence that any named plaintiff ever bought a policy from either company or was ever treated by a doctor holding such a policy), aff'd, 438 U.S. 531, 98 S. Ct. 2923, 57 L. Ed. 2d 932 (1978); In re Organogenesis Sec. Litig., 241 F.R.D. 397, 403-05 (D. Mass. 2007) (ruling that named plaintiff did not have standing to maintain class claims against defendant whose individual conduct could not have caused any harm to the named plaintiff).

FWK's Standing to Litigate Class Claims

This court finds that FWK also has standing to litigate claims arising out of Sanofi's postJune 2016 Conduct. The gravamen of the plaintiff's complaint is that Sanofi engaged in an
anticompetitive scheme to monopolize the market for insulin glargine and charge
supracompetitive prices for Lantus and Lantus SoloSTAR by improperly listing patents in the
FDA's Orange Book and filing wrongful infringement actions against would-be competitors.

The allegedly improper conduct began long before the start of the class period, when Sanofi
established a practice of listing patents in the Orange Book that failed to meet the listing
requirements. (See SAC ¶¶ 239-42). It continued unabated well into 2017, when Sanofi filed
the last of its three infringement actions against a potential competitor. (See id. ¶¶ 434-35;
444-45). Although Kerr's last purchase of Lantus products occurred in May 2016, both Kerr and
other members of the class are alleged to have suffered the same type of injury by having to
pay supracompetitive prices for Lantus products as a result of this continuing scheme. (Id. ¶
514). Under such circumstances, FWK and the class have a common interest in litigating claims
arising from Sanofi's course of conduct.

This court finds the cases addressing standing in securities class action cases based on a common fraudulent scheme to be most analogous to the instant situation. Courts in those cases have held that the named plaintiff does not have to be harmed by each misrepresentation at issue to have standing to pursue a class action where other members of

⁹ This court recognizes that the plaintiff dropped its claims of serial petitioning and sham litigation in connection with its appeal to the First Circuit of this court's prior order dismissing the SAC. See In re Lantus, 950 F.3d at 6 n.3, 14-15. Nevertheless, the plaintiff may continue to pursue its challenges to Sanofi's infringement actions pursuant to its contention that Sanofi engaged in on overall scheme of anti-competitive conduct.

the class have been harmed as part of a continuous, common scheme. See, e.g., In re Evergreen Ultra Short Opportunities Fund Sec. Litig., 275 F.R.D. 382, 387 (D. Mass. 2011) (concluding that lead plaintiffs had standing to sue on behalf of a class, despite not having purchased stock until nearly 15 months after the beginning of the class period, "because their claims [arose] out of the same allegedly misleading course of conduct as the claims of the class members who made earlier purchases"); In re Organogenesis, 241 F.R.D. at 403 (concluding that named plaintiff had standing to litigate alleged misrepresentations made by defendant after named plaintiff's last purchase of stock "because in proving reliance on the common course of misrepresentation, the plaintiff would necessarily prove the absent class members['] case as well as his own"); Crowell v. Ionics, Inc., 343 F. Supp. 2d 1, 13-14 (D. Mass. 2004) (finding that a "common course of conduct" inquiry is appropriate in assessing standing, and concluding that lead plaintiff had standing to assert securities fraud claims arising from misstatements made after lead plaintiff last purchased defendant's stock where misstatements allegedly occurred as part of a fraudulent scheme that began before plaintiff's purchase). In the instant case, FWK has alleged that the post-June 2016 Conduct of listing patents in the Orange Book and pursuing meritless litigation was a continuation of a scheme devised years earlier, while Kerr was still operating. Allowing FWK to pursue claims involving a common course of conduct that extended beyond its last purchase is consistent with the principle that the named plaintiff does not have to have claims that are identical to all other class members. See In re Asacol, 907 F.3d at 49. It also appropriately focuses the inquiry on whether the plaintiff has a sufficient personal stake in the adjudication of the class members' claims. See id. Since the plaintiff has the same interest in proving the alleged scheme with respect to all the

Orange Book listings, and with respect to all the related litigation brought by Sanofi, it has standing to maintain this action relating to Sanofi's post-June 2016 Conduct.

Sanofi's Challenge to the Alleged Scheme

Sanofi disputes that FWK's allegations of a continuing scheme or course of conduct are sufficient to support standing in this case. As Sanofi reasons,

FWK cannot establish its standing to challenge the Conduct, which FWK concedes caused it no injury, by bootstrapping it to conduct that allegedly did cause FWK injury (the Lilly lawsuit and related patent listings (collectively, the "Lilly lawsuit")) and labeling all of that conduct a single "scheme" . . . This is not a case (as FWK argues) where different plaintiffs merely were injured by the same conduct at different times. To the contrary, the Lilly lawsuit and the Merck and Mylan lawsuits are separate and distinct actions taken by Sanofi; they cannot be grouped as the same conduct or course of conduct. Rather, they are different legal actions filed at different times against different parties based on different FDA applications for different proposed new drug products that allegedly infringed a different mix of Sanofi patents ... Most importantly, Sanofi only filed its actions against Merck and Mylan after FWK (as Kerr's proxy) had gone out of business, thus foreclosing any possibility that those lawsuits could have injured FWK.

(Def. Reply Mem. at 2-3 (emphasis in original)).

This court finds the defendant's argument unpersuasive. As an initial matter, this court finds that Sanofi's characterization of the infringement actions as separate and distinct events rather than part of the same course of conduct that caused all of the class members harm constitutes an inaccurate reading of the Second Amended Complaint. Throughout its 125-page complaint, FWK describes the defendant's actions in listing patents in the Orange Book and filing lawsuits against potential competitors as an ongoing, anticompetitive scheme to monopolize the market for insulin glargine and charge artificially inflated prices for its products.

Allegedly, in order to carry out this scheme, Sanofi took advantage of the Hatch-Waxman

Amendments to game the system for listing patents and delaying FDA approval of competing drug products.

FWK also alleges that Sanofi's conduct with respect to the three infringement lawsuits was essentially the same. FWK alleges that in each case Sanofi filed suit after receiving the aspiring competitor's Paragraph IV certifications, thereby triggering the 30-month statutory stay mandated by the Hatch-Waxman Amendments. It also alleges that Sanofi's claims of infringement in all three cases were meritless, based on patents that should not have been listed in the Orange Book, and motivated by a desire to stifle competition rather than a legitimate concern for its intellectual property.

Sanofi's argument is also defeated by the fact that many of the patents giving rise to Sanofi's claims in the Lilly litigation were also at issue in the Merck and Mylan cases, and had been listed in the Orange Book prior to June 2016 as part of Sanofi's alleged practice of submitting patents to the FDA for listing even though they failed to meet the statutory listing requirements. (See SAC ¶¶ 325, 344, 356, 406-07, 411, 418, 421, 425, 434). Taking these facts as true and drawing all reasonable inferences in FWK's favor as this court is obliged to do supports the conclusion that Sanofi engaged in a continuing course of conduct aimed at blocking competition in the market for insulin glargine and keeping the price of Lantus products high. Because the alleged facts surrounding Sanofi's post-June 2016 Conduct are part of the same anticompetitive scheme as its earlier conduct, FWK has ample incentive to litigate claims based upon that Conduct.

The effects of the alleged scheme on the plaintiff and members of the putative class further supports the conclusion that FWK's interests are aligned with class members who purchased Lantus products after June 2016. As described above, FWK claims that "Sanofi's overarching anticompetitive scheme impaired and delayed the sale of competing insulin glargine products in the United States, and unlawfully enabled Sanofi to sell Lantus and Lantus SoloSTAR products at artificially inflated prices." (Id. ¶ 452). It further claims that Sanofi's conduct, including its improper patent listings and three infringement suits, caused the plaintiff and all members of the class to pay substantially higher prices for Lantus products than they would have paid in the absence of its conduct, and sustain "substantial losses and damage . . . in the form of overcharges[.]" (Id. ¶¶ 452-60). By its demand for relief, FWK is seeking, among other things, "class damages (i.e., three times overcharges) in an amount to be determined at trial[.]" (Id. ¶ 515). In an antitrust action such as this one "all plaintiffs who were forced to pay a higher price in the absence of generic competition have a substantial and shared interest in proving that the higher price was the result of unlawful monopolizing conduct that is redressable by an award of damages." In re Asacol, 907 F.3d at 49. See also Nexium I, 968 F. Supp. 2d at 407 (holding that "[a]ll members of the putative class [had] a common interest in litigating claims arising from Defendants' allegedly anticompetitive collusion designed to cause End-Payors to pay supracompetitive prices across several states" even though named End-Payors made payments in some but not all of those states). Therefore, FWK has a "personal stake in the adjudication of the class members' claims[.]" In re Asacol, 907 F.3d at 49.

In arguing that the plaintiff's allegations of an overall scheme are insufficient to support Article III standing in this case, Sanofi compares FWK's theory to the facts in <u>Abato v. Marcam</u>

Corp., 162 F.R.D. 8 (D. Mass. 1995), and argues that the Abato court's reasoning should dictate the outcome here. (Def. Mem. at 6-8). Abato is a securities class action in which the plaintiff claimed that the defendant made materially false and misleading statements about its financial condition as part of a "concerted scheme to expand [its] product line through acquisitions using artificially inflated stock." Abato, 162 F.R.D. at 10. There the court considered whether the plaintiff had standing to maintain a claim under the federal securities laws where the challenged conduct occurred after the plaintiff's purchase of the defendant's stock. Id. The court declined to follow cases which held "that a named plaintiff may represent claims arising from alleged misstatements made after her purchase or sale if the misstatements were made in furtherance of a 'common course' of conduct to defraud." Id. (emphasis in original; citations omitted). The court determined that those cases and the "common course of conduct" theory applied to questions of class certification under Fed. R. Civ. P. 23 but were "inapposite in the standing context." Id. at 10-11. The court went on to conclude that even if it were assumed the "common course of conduct" theory did apply to questions of standing, the plaintiff's claim would still fail because the transactions at issue were "two entirely separate events" consisting of "different assets, different accounting rules, entirely different time periods, and different alleged misrepresentations." Id. at 11.

This court declines to apply the <u>Abato</u> court's reasoning to this case. As an initial matter, Judge Young, who decided Abato, was subsequently "persuaded that cases . . . which apply a 'common course of conduct' analysis to standing questions, are better reasoned than cases that require the lead plaintiff to have purchased on the last day of the class period" and that, "[i]n many ways, a 'common course of conduct' test is more appropriate in the standing

inquiry than in the certification inquiry." <u>Crowell</u>, 343 F. Supp. 2d at 14. In addition, more recent decisions from courts within this circuit have adopted the "common course of conduct" test as part of their standing analysis. See, e.g., In re Evergreen Ultra Short Opportunities Fund, 275 F.R.D. at 387 (ruling that lead plaintiffs could sue on behalf of the class, even though they did not purchase stock for nearly 15 months after the start of the class period, where plaintiffs' claims arose "out of the same allegedly misleading course of conduct as the claims of class members who made earlier purchases"). See also Sheet Metal Workers Local No. 20 Welfare & Benefit Fund v. CVS Health Corp., 221 F. Supp. 3d 227, 236 (D.R.I. 2016) (finding that named plaintiffs and putative class members had a collective interest in litigating their claims together where plaintiffs alleged that defendant engaged in a scheme involving the fraudulent reporting of prices for generic drugs). Moreover, since Abato was decided, the First Circuit has clarified that courts considering Article III standing in the class action context should focus their analysis on the interest of the named party in litigating the class members' claims. See In re Asacol, 907 F.3d at 48-49. For the reasons stated previously, this court concludes that FWK has a sufficient personal stake in litigating antitrust claims arising out of the defendant's Conduct to establish standing to pursue those claims.

Sanofi's Challenge to Identity of Claims

This court's conclusion is not altered by Sanofi's assertion that FWK lacks standing because it cannot show that success on its claims arising out of the pre-June 2016 conduct "will more or less dictate success" on class members' claims stemming from the later Conduct. (Def. Reply Mem. at 9 (quoting <u>In re Asacol</u>, 907 F.3d at 49) (emphasis omitted)). The Article III standing requirement erects no "impediment to [a] named plaintiff['s] ability to litigate as class

representative[] materially identical claims by other persons under the same laws under which the named plaintiffs' claims arise." In re Asacol, 907 F.3d at 47. Here, there is no question that FWK's causes of action are the same for itself and all members of the proposed class. FWK is seeking to hold Sanofi liable to all class members for harm resulting from monopolization and attempted monopolization in violation of section 2 of the Sherman Act. Although the facts underlying the plaintiff's claims and those of the class differ in the sense that Sanofi listed additional patents in the Orange Book and commenced litigation against two additional parties after June 2016, the record establishes that the anticompetitive nature of Sanofi's conduct remained the same throughout both time periods. If FWK is able to show that Sanofi's actions prior to June 2016 were part of an anticompetitive scheme to foreclose competition in the market for insulin glargine, and that it was charged supracompetitive prices for Lantus and Lantus SoloSTAR as a result, FWK may be able to establish the claims of class members who were harmed by having to pay supracompetitive prices for Lantus and Lantus SoloSTAR after June 2016 as a result of the same course of conduct. See Glass Dimensions, Inc. v. State Street Bank & Trust Co., 285 F.R.D. 169, 174-75 (D. Mass. 2012) (finding that named plaintiff had standing to sue on behalf of a class that included claims relating to 260 lending funds, even though plaintiff only invested in three of those funds, where alleged injury to all class members was based on defendant's management of all 260 funds). Because this court finds that FWK's claims are materially identical to the claims of class members who purchased Lantus products after June 2016, the plaintiff has standing to pursue all its claims at this stage in the proceedings.

Sanofi's reliance on the First Circuit's decision in Plumbers' Union does not warrant a different result. In that case, institutional investors who purchased trust certificates representing mortgage-backed securities brought a putative class action against eight trusts, the "depositor" that organized the trusts, the trusts' underwriters and various individuals for violations of federal securities laws. Plumbers' Union, 632 F.3d at 765-67. The plaintiffs claimed that the offering documents for the trusts contained false and misleading statements, as a result of which the true value of their securities was less than what they paid for them. Id. at 767. The First Circuit held that the named plaintiffs had no standing to pursue claims against six of the eight trusts because no named plaintiff had purchased certificates in those trusts. Id. at 771. Accordingly, those trusts and the defendants "connected to only those six trusts" were properly dismissed. Id. The court went on to find that the depositor was a properly named defendant, but it held that the named plaintiffs had no standing to pursue claims against the depositor "so far as they are based on the six trusts whose certificates were purchased by no named plaintiff[,]" because "the named plaintiffs [had] no stake in establishing liability as to misconduct involving sales of those certificates." Id. In arriving at this conclusion, the First Circuit quoted the following statement from the Supreme Court's decision in Blum v. Yaretsky, 457 U.S. 991, 102 S. Ct. 2777, 73 L. Ed. 2d 534 (1982): "Nor does a plaintiff who has been subject to injurious conduct of one kind possess by virtue of that injury the necessary stake in litigating conduct of another kind, although similar, to which he has not been subject." Id. (quoting Blum, 457 U.S. at 999, 102 S. Ct. at 2783). Thus, the Court indicated that the nature of the defendant's conduct, and the effects of that conduct on the named plaintiff and members of the putative class, are critical to the standing analysis.

The facts of Plumbers' Union are distinguishable from the circumstances presented in this case. In <u>Plumbers' Union</u>, the six trust defendants that were dismissed from the case were "not liable to the named plaintiffs on any claims" because they were "not implicated in any of the wrongs done to the named plaintiffs." Id. at 769. There is no dispute in the instant case that FWK has alleged a personal injury as a result of the defendant's anticompetitive scheme. Similarly, the First Circuit in Plumbers' Union limited the claims asserted against the depositor to the trusts from which the named plaintiffs had purchased certificates because "the named plaintiffs [had] no stake" in pursuing claims based on sales of those certificates. <u>Id.</u> at 771. Here, in contrast, FWK is seeking to hold Sanofi liable for engaging in an ongoing scheme to monopolize the market for insulin glargine, with an injury focused on the defendant's conduct in foreclosing competition and charging purchasers supracompetitive prices for its drug products. Under the circumstances presented in this case, FWK has an identity of interest with the proposed class of purchasers "who were forced to pay a higher price" as a "result of unlawful monopolizing conduct[.]" In re Asacol, 907 F.3d at 49. See also Nexium I, 968 F. Supp. 2d at 407 (concluding that named plaintiffs had a common interest with proposed class of End-Payors who allegedly paid supracompetitive prices as a result of defendants' anticompetitive conduct). Plumbers' Union does not defeat FWK's standing to pursue claims arising out of the Conduct.

Finally, this court notes that a ruling in FWK's favor appears consistent with the trend among courts examining standing in similar contexts. See, e.g., In re Asacol, 907 F.3d at 51 (noting direction from the Supreme Court suggesting that "once the named plaintiff establishes injury and membership in a class, the inquiry should shift" from the question of justiciability to

the issue of class certification under Fed. R. Civ. P. 23); Nexium II, 777 F.3d at 32 ("It is undisputed that the named plaintiffs have shown that they were overcharged for at least one Nexium transaction during the class period, establishing standing"); Sheet Metal Workers, 221 F. Supp. 3d at 236 (noting that once a named plaintiff demonstrates standing to bring its own claims against the defendant, the issue of standing to bring claims on behalf of a class "would be appropriately, and more efficiently, addressed at the class certification stage"); Glass Dimensions, 285 F.R.D. at 175 (explaining that once plaintiff establishes his own standing against a defendant, the question whether the plaintiff should be able to represent a putative class against that defendant depends on the plaintiff's ability to meet the class certification requirements of Fed. R. Civ. P. 23). Accordingly, this court finds that FWK has alleged sufficient facts to establish standing to pursue all of its claims against the defendant, including claims based on the alleged post-June 2016 Conduct.

IV. <u>CONCLUSION</u>

For all the reasons detailed herein, "Defendant Sanofi-Aventis U.S. LLC's Motion to Dismiss Certain Claims for Lack of Article III Standing" (Docket No. 152) is DENIED.

<u>/ s / Judith Gail Dein</u>
Judith Gail Dein
United States Magistrate Judge